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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,066	12/07/2001	David A. Schwartz	875.010US2	2746

21186 7590 06/06/2005

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EXAMINER

MURPHY, JOSEPH F

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,066

Applicant(s)

SCHWARTZ ET AL.

Examiner

Joseph F. Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30, 32-40 is/are pending in the application.
4a) Of the above claim(s) 1-16, 20-27, 29 and 30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 17-19, 28, 32-40 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 1-30, 32-40 are pending. Claims 1-16, 20-27, 29-30 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 17-19, 28, 32-40 are under consideration.

Response to Amendment

The rejection of claims 28 and 32-39 under 35 USC 112 second paragraph has been withdrawn based on Applicant's arguments.

Remaining issues are set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 32-39 stand rejected, new claim 40 is rejected, and claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rock et al. (1998) in view of Morris et al. (1995) for reasons of record set forth in the Office Action of 12/15/2005.

The claims are drawn to methods of detecting polymorphisms in human TLR4 through amplification of the nucleic acid with probes comprising restriction sites. The claims are unpatentable because Rock teaches the molecular cloning of five human Toll-like receptors--named TLRs 1-5. The method used to clone the TLR4 gene was the use of nucleic acid primers. The method as written in the claims only requires the use of TLR4 "specific" probes. This limitation reads on random primers, which would be expected to bind any sequence.

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Additionally, the claim has an amplification step, but no comparison or determining step.

Therefore the claim as written reads on a method of amplifying TLR4 DNA, which is taught by Rock. The Rock reference does not teach the use of primers comprising engineered restriction sites. However, the Morris reference teaches the use of random primers that comprise restriction sites (see Figure 2). Thus it would have been obvious to one of skill in the art at the time the invention was made to practice a method of detecting polymorphisms in human TLR4 through amplification of the nucleic acid with probes comprising restriction sites. The motivation is provided in the Morris reference which teaches that the directional random priming strategy using probes comprising restriction sites produces high cloning efficiencies, and directionally cloned inserts (Morris at 4).

Applicant argues that the rejection is inapposite because neither reference teaches the determination of TLR4 polymorphisms, nor do they teach the detection of polymorphisms at positions 299 or 399 of TLR4. However, claim 28 sets forth in the preamble that the method is to detect a polymorphism in the TLR4 gene, but there is no difference between this method and a standard sequence determination, as set forth in Rock et al. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). Here, the preamble does not result in a manipulative difference in the claimed process over the prior art sequencing method, since no step sets forth the assigning of the haplotype pair.

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Conclusion

No claim is allowed.

Advisory Information

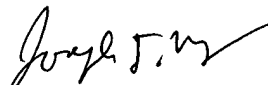
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Primary Examiner
Art Unit 1646
May 27, 2005


**JOSEPH MURPHY
PATENT EXAMINER**